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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/523,908

01/28/2005

Armin Breitenbach

6102-000075/US

9463

28997 7590 12/09/2009
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EXAMINER

AHMED, HASAN SYED

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

12/09/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/523,908	Applicant(s) BREITENBACH ET AL.	
	Examiner HASAN S. AHMED	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-36, 38-41, 45-48 and 52-56 is/are pending in the application.
- 4a) Of the above claim(s) 38-40, 45-48 and 52-56 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-36 and 41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/20/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of applicants': amendment, response, RCE, and IDS, all filed on 20 October 2009.

* * * * *

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 20 October 2009 has been entered.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 28-32, 34-36, and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,658,975 ("Ulman") in view of U.S. Patent No. 6,620,429 ("Müller").

Ulman teaches a hot-melt pressure sensitive adhesive composition comprising:

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- the transdermal therapeutic system of instant claim 28 (see col. 7, lines 9-36);
- the drug containing adhesive matrix of instant claim 28 (see col. 7, lines 16-17);
- the hot-meltable adhesive of instant claim 28 (see col. 2, lines 18-30);
- the softener (wax) of instant claim 28 (see col. 2, line 26);
- the drug dispersed in adhesive of instant claim 29 (see col. 7, lines 16-17);
- the amine-resistant silicone (polydimethyl siloxane) adhesive of instant claims 31 and 41 (see col. 4, line 5);
- the softener (wax) of instant claims 31 and 41 (see col. 2, line 26);
- the organic wax (siloxylated polyether wax) of instant claim 32 (see col. 2, line 26);

While Ulman does not explicitly teach all concentrations of drug recited in instant Claims 34-36, it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable percentages through routine or manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art.

Moreover, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine

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experimentation.” *In re Aller*, 220 F.2d 454, 456; 105 USPQ 233, 235 (CCPA 1955). Applicants have not demonstrated any unexpected or unusual results, which accrue from the instant percentage ranges. The silicone resin is added in an amount of up to 70% (see col. 3, line 44) and the softener is added in an amount of up to 20% (see col. 2, line 25), reading on instant claim 41. Ulman clearly teaches use of the disclosed hot-melt composition for transdermal drug delivery (see col. 7, lines 9-36). The concentration ranges recited in instant claims 34-36 are broad and would be obvious for a transdermal formulation. Further, Müller teaches a rotigotine concentration of about 20% (see Example 2), overlapping with the concentration ranges recited in claims 34-46.

The Ulman reference does not address the viscosity of instant claim 18. The Ulman composition, like the instantly claimed composition, is comprised of a drug-containing adhesive matrix and a softener (see above). Properties are the same when the structure and composition are the same. Thus, burden shifts to applicant to show unexpected results, by declaration or otherwise. *In re Fitzgerald*, 205 USPQ 594. In the alternative, the claimed properties would have been present once the composition was employed in its intended use. *In re Best*, 195 USPQ 433.

The process disclosed in claim 30 is not essential to a determination of patentability of the composition disclosed in the claim. The patentability of product-by-process claims is based on the product itself. “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of

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production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Ulman explains that a transdermal therapeutic system in the form of a hot-melt adhesive and a softener is beneficial because, "...the amount of drug released can be increased or controlled." See col. 1, line 67 - col. 2, line 1.

Ulman differs from the instant application in that it does not disclose the rotigotine in base form of instant claims 28 and 37. Use of rotigotine ((-)-5, 6, 7, 8,- tetrahydro-6-[propyl[2-(2-thienyl)-ethyl]amino]-1-naphthol hydrochloride) in a transdermal formulation was known in the art at the time the instant application was filed as disclosed by Müller (see examples 1 and 2). The rotigotine in the form of a base is formed when the rotigotine of Müller's examples 1 and 2 is mixed with sodium metasilicate (see col. 3, lines 38-44).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose a transdermal therapeutic system comprising a rotigotine-containing adhesive matrix and a softener, as taught by Ulman in view of Müller. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a composition because the amount of drug released from the transdermal formulation can be increased or controlled, as explained by Ulman.

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2. Claims 28 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,658,975 ("Ulman") in view of U.S. Patent No. 6,620,429 ("Müller"), further in view of U.S. Patent No. RE 36,754 ("Noel").

Ulman teaches a hot-melt pressure sensitive adhesive composition (see above). Müller teaches a transdermal formulation comprising rotigotine (see above). Ulman and Müller differ from the instant application in that they do not disclose the ceresine or ozokerite of instant claim 33, however, use of ceresine and ozokerite in hot-melt silicone-based transdermal therapeutic systems was known in the art at the time the instant application was filed, as disclosed by Noel (see abstract and col. 5, line 1).

Noel explains that waxes such as ceresine and ozokerite function, "...to decrease the dynamic viscosity of the hot-melt pressure sensitive adhesive at temperatures equal to or below about 200°C." See col. 5, lines 12-14.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose a transdermal therapeutic system comprising a rotigotine-containing adhesive matrix and ceresine or ozokerite, as taught by Ulman in view of Müller further in view of Noel. One of ordinary skill in the art at the time the invention was made would have been motivated to use ceresine or ozokerite in a transdermal therapeutic system because such waxes decrease dynamic viscosity of hot-melt pressure sensitive adhesives at temperatures equal to or below about 200°C, as explained by Ulman.

* * * * *

Double Patenting

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The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 28-36 and 41 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 of copending Application No. 10/630,633 ('633). Although the conflicting claims are not identical, they are not patentably distinct from each other because '633 claims a transdermal therapeutic system made up of a hot-melttable adhesive comprising Rotigotine (see claim 1) and at least one softener (see claim 3).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

*

2. Claims 28-36 and 41 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 15-36 of

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compending Application No. 10/139,894 ('894). Although the conflicting claims are not identical, they are not patentably distinct from each other because '894 claims a transdermal therapeutic system comprising Rotigotine (see claim 15) and two or more silicone adhesives (see claim 16).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

*

3. Claims 28-36 and 41 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 12 of compending Application No. 10/140,096 ('096). Although the conflicting claims are not identical, they are not patentably distinct from each other because '096 claims a transdermal therapeutic system comprising Rotigotine (see claim 15).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

*

4. Claims 28-36 and 41 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of compending Application No. 10/623,864 ('864). Although the conflicting claims are not identical, they are not patentably distinct from each other because '864 claims a transdermal therapeutic system comprising Rotigotine (see claim 1).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

*

5. Claims 28-36 and 41 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-120 of copending Application No. 11/239,701 ('701). Although the conflicting claims are not identical, they are not patentably distinct from each other because '701 claims a transdermal therapeutic system comprising Rotigotine (see claims 1 and 2).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

*

6. Claims 28-36 and 41 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-110 of copending Application No. 11/239,772 ('772). Although the conflicting claims are not identical, they are not patentably distinct from each other because '772 claims a transdermal therapeutic system comprising Rotigotine (see claims 1 and 2).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

* * * * *

Response to Arguments

Applicants' arguments filed on 20 October 2009 have been fully considered but they are not persuasive.

35 USC 103

Applicants argue that Ulman and Müller are incompatible because Ulman is designed for improved performance with hydrophilic drugs while Müller teaches a lipophilic drug.

Examiner agrees that Ulman teaches a composition with "improved hydrophilic characteristics" (see, e.g., col. 2, line 5 and col. 7, line 40). Ulman further teaches that the improved hydrophilic characteristics lead to the advantage that, "higher dosages of hydrophilic drugs can be employed without destroying the pressure sensitive adhesive" (see col. 1, lines 65-67) and "quicker delivery of drugs that are hydrophilic in nature" (see col. 7, lines 40-41). However, examiner respectfully submits that nowhere in the reference is it stated that only hydrophilic drugs can be employed in the disclosed composition, or that lipophilic drugs cannot be used in the composition. The section of the reference which describes delivery of active agents (see col. 7, lines 9-36) repeatedly recites delivery of a generic "bioactive agent" without any qualifier, such as "hydrophilic bioactive agent." Thus, while the Ulman composition does teach certain advantages when using hydrophilic drugs, the reference does not implicitly or explicitly suggest that hydrophilic drugs are used with the disclosed composition exclusively.

Applicants argue that there is a strong presumption that the Ulman composition would work only with hydrophilic drugs (see remarks, page 10). However, the arguments of counsel cannot take the place of evidence in the record. In *re* Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); In *re* Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). See MPEP § 2145. Further, Attorney

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argument is not evidence unless it is an admission, in which case, an examiner may use the admission in making a rejection. See MPEP § 2129 and § 2144.03 for a discussion of admissions as prior art.

Provisional Obviousness-Type Double Patenting

Applicants argue that the co-pending applications do not recite the viscosity that is recited in instant claim 28.

Examiner respectfully submits that the viscosity of a composition may be determined by optimization or routine experimentation by a person of ordinary skill in the art.

☆

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571)272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. S. A./
Examiner, Art Unit 1615